Notice of Allowability	Application No.	Applicant(s)	
	10/737,270	THOMAS ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *1/24/05*.
2. ☒ The allowed claim(s) is/are *12-17*, renumbered 1-6, respectively.
3. ☒ The drawings filed on *16 December 2003* are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date attached.
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan Michaud on April 27, 2005.

2. This Office Action is responsive to Applicant's response dated January 24, 2005. All rejections of record are withdrawn in view of Applicant's amendment and remarks. Claims 12-17 (numbered 1-6, respectively) are allowed.

3. The application has been amended as follows:

In the Title: ~~Passive~~ Active immunization against Clostridium difficile disease

In the Abstract: ~~Passive~~ *Active* Immunization Against Clostridium Difficile Disease

Abstract of the Disclosure

The invention provides active ~~and passive~~ immunization methods for preventing and treating *Clostridium difficile* infection, which involve percutaneous administration of *C. difficile* toxin-neutralizing polyclonal immune globulin, *C. difficile* toxoids, or combinations thereof. Also provided by the invention are *C. difficile* toxoids, *C. difficile*

toxin-neutralizing polyclonal immune globulin, and methods of identifying subjects that produce *C. difficile* toxin-neutralizing polyclonal immune globulin.

In the Specification: ~~Passive~~ *Active* Immunization Against Clostridium Difficile Disease

This is a continuation-in-part of U.S. Serial No. 09/815,452, filed March 22, 2001 ~~(pending)~~ (U.S. Patent No. 6,680,168), which is a continuation of U.S. Serial No. 09/176,076, filed October 20, 1998 (U.S. Patent No. 6,214,341 B1), which claims priority from U.S. Serial No. 60/062,522, filed on October 20, 1997 (abandoned).

In the claims:

Claim 1. (currently amended) A method of preventing or treating symptomatic *Clostridium difficile* infection in a human patient, said method comprising percutaneously administering ~~a~~ an effective amount of a clostridial ~~toxin or~~ toxoid to said human patient.

Claim 2. (currently amended) The method of claim ~~12~~ 1, wherein said ~~toxin or~~ toxoid is a *Clostridium difficile* ~~toxin or~~ toxoid.

Claim 3. (currently amended) The method of claim ~~12~~ 1, wherein said patient has or is at risk of developing recurrent *Clostridium difficile* associated diarrhea.

Claim 4. (currently amended) The method of claim ~~12~~ 1 wherein said clostridial ~~toxin or~~ toxoid is intramuscularly, intravenously, or subcutaneously administered to said human patient.

Claim 5. (currently amended) The method of claim ~~12~~ 1, wherein said patient does not have, but is at risk of developing symptomatic *Clostridium difficile* infection.

Claim 6. (currently amended) The method of claim ~~12~~ 1 wherein said patient has symptomatic *Clostridium difficile* infection.

4. The following is an examiner's statement of reason for allowance. The prior art of record falls because the instant application has priority to October 20, 1997. There is no prior art that neither teaches nor suggests a method of preventing or treating symptomatic *Clostridium difficile* infection in a human patient, wherein the method comprises percutaneously administering an effective amount of a clostridial toxoid to a human patient.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakia Tongue

L.F.S.
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Clean Copy of Title

Active immunization against Clostridium difficile disease

Clean Copy of Abstract

~~Passive~~ *Active* Immunization Against Clostridium Difficile Disease

Abstract of the Disclosure

The invention provides active immunization methods for preventing and treating *Clostridium difficile* infection, which involve percutaneous administration of *C. difficile* toxin-neutralizing polyclonal immune globulin, *C. difficile* toxoids, or combinations thereof. Also provided by the invention are *C. difficile* toxoids, *C. difficile* toxin-neutralizing polyclonal immune globulin, and methods of identifying subjects that produce *C. difficile* toxin-neutralizing polyclonal immune globulin.

Clean Copy of Specification

Active Immunization Against *Clostridium Difficile* Disease

This is a continuation-in-part of U.S. Serial No. 09/815,452, filed March 22, 2001 (U.S. Patent No. 6,680,168), which is a continuation of U.S. Serial No. 09/176,076, filed October 20, 1998 (U.S. Patent No. 6,214,341 B1), which claims priority from U.S. Serial No. 60/062,522, filed on October 20, 1997 (abandoned).

Clean Copy of Claims

1. A method of preventing or treating symptomatic *Clostridium difficile* infection in a human patient, said method comprising percutaneously administering an effective amount of a clostridial toxoid to said human patient.

2. The method of claim 1, wherein said toxoid is a *Clostridium difficile* toxoid.

3. The method of claim 1, wherein said patient has or is at risk of developing recurrent *Clostridium difficile* associated diarrhea.

4. The method of claim 1, wherein said clostridial toxoid is intramuscularly, intravenously, or subcutaneously administered to said human patient.

5. The method of claim 1, wherein said patient does not have, but is at risk of developing symptomatic *Clostridium difficile* infection.

6. The method of claim 1 wherein said patient has symptomatic *Clostridium difficile* infection.